

REMARKS

Reconsideration is requested.

Claims 1-15 and 23 have been canceled, without prejudice.

The details of claim 23 have been added to claim 16 and claim 16 has been revised for clarity, without prejudice. Claim 20 has been amended to include the concentration described, for example, at page 9, lines 14-15 of the specification. Claim 34 has been added and finds basis in the specification, for example, at page 9, lines 28-29 of the specification. No new matter has been added.

Claims 16-22 and 24-34 are pending.

The Examiner is requested to appreciate that the claimed invention provides a process which requires that at a stage which precedes the end of fermentation the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms. The claimed process step requires that:

(i) the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-organism, and

(ii) the carbon source is still added such that the rate of addition is greater than zero.

The Examiner is further urged to appreciate that the claimed feed profile requires that the carbon source is added during the recited stage, i.e. it is added at a certain rate. It is furthermore to be appreciated that this rate is below the rate of consumption of the carbon source by the micro-organism. This means that - while the addition of carbon source is continued - the concentration of carbon source decreases over time (as rate of addition of carbon source is below the rate of consumption by the micro-organisms)

The applicants have discovered that the claimed process requirements result in a increased ARA content in the oil. This is described, for example, on page 4, lines 15 and 16 of the specification. This is further shown in the examples, such as in examples 3 and 4 according to the invention, the ARA content of the oil is 50.8% and 54.5% ARA respectively compared to 36.8% and 36.7% ARA that is found in comparative experiments 1 and 2.

The Section 112, first paragraph "enablement", rejection of claims 1, 2, 4-6 and 16-33 stated in ¶3.a. of the Office Action dated April 30, 2007 is believed to be obviated by the above amendments. Specifically, the recitation of the specific micro-organism and ARA in claim 16 is believed to obviate this basis for the rejection.

As for the basis for the rejection stated in ¶3.b. of the Office Action dated April 30, 2007, the applicants believe the ordinarily skilled person will understand that at least part of the arachidonic acid of claims 30-33 is present as fatty acid contained in the triglyceride.

As appears to be acknowledged by the Examiner, and well-known in the art, a triglyceride is a glyceride in which the glycerol is esterified with three fatty acids. In the field of oils and lipids, it is generally accepted and widely understood that the fatty acids that are contained in the triglyceride are referred to as fatty acids. Hence, the ordinarily skilled person, reading claims 30-33 will understand that at least part of the arachidonic acid is contained in the triglyceride. This is also fully supported by the description at, for example, page 12, lines 21-31 which describes that the oil can have a triglyceride content of 90-100%, and at least 50% ARA. Moreover page 13, line 4 describes polyunsaturated fatty acids (PUFAs) present in the tryglyceride backbone.

Finally, with regard to the basis of the rejection stated in ¶3.c. of the Office Action dated April 30, 2007, consideration of the following is requested.

The applicants submit that the specifically exemplified DS 30340 micro-organism is not necessary for performing the claimed invention. The specific strain DS 30340 is not necessary for performing the invention. The invention can be worked using any *Mortierella* strain.

As discussed above, the claimed invention defines a process wherein the carbon feed produces an ARA content in the oil which is increased compared to the situation wherein the carbon feed is not applied in the claimed manner. The claimed process is based on the applicants discovery that under these conditions ARA is formed in preference to other fatty acids, or that the cells metabolise or consume fatty acids other than ARA first, see e.g. page 4, lines 15-16. This principle, and accordingly the advantage of increased ARA-contents, is not limited to the specific exemplified DS 30340 strain, and is equally well applicable to any *Mortierella* strain. There is nothing in the specification which suggests the limitation of the claimed discovery and the effect of the invention to the specific DS 30340 strain. Accordingly, the applicants respectfully request reconsideration and withdrawal of the Examiner's assertion that strain DS 30340 "is required to practice the claimed invention(s) as recited in the claims".

Withdrawal of the Section 112, first paragraph "enablement", rejection is requested.

The Section 102 rejection of claims 1, 2 and 4-6 over Suzuki (U.S. Patent No. 4, 783,408), is moot in view of the above.

To the extent not made moot by the above amendments, the Section 102 and Section 103 rejections of claims 1, 2, 4-6 and 16-28 over Barclay (U.S. Patent No. 5,882,703), is traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments.

The cited patent does not disclose or suggest adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the claims. The Examiner is urged to appreciate that the claims define a process. An anticipatory reference must teach each and every aspect of the claimed invention. The cited patent fails to literally or inherently teach the claimed process requirements. Withdrawal of the Section 102 rejection is requested.

Examples 1-5 of the cited patent is understood to describe culturing *Mortierella schmuckeri* in shake flasks wherein the carbon source is added at once prior to the onset of the experiment.

Example 6 of the cited patent is understood to describe culturing *Mortierella schmuckeri* in a fermentor. However, no feed profile for the carbon source is disclosed other than that all carbon source is added at once, i.e. a medium having a specific composition is prepared (see col. 14, lines 57-61). There is no teaching or suggestion in the cited patent that a carbon source is added during the course of the fermentation.

There is no teaching or suggestion in the cited patent of adding of carbon source at a certain rate, let alone adding of a carbon source at a rate below the rate of consumption by the micro-organisms, as claimed.

In conclusion, the cited patent does not teach or suggest adding a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as claimed.

Even less does Barclay provide any teaching or suggestion that adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms results in a increased ARA content in the oil, as claimed.

Withdrawal of the Section 102 and Section 103 rejections based on Barclay is requested.

To the extent not made moot by the above amendments, the Section 102 and Section 103 rejections of claims 1, 2, 4-6 and 16-28 over Higashiyama (U.S. Patent No. 6,746,857), , is traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments.

The cited patent fails to teach or suggest adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the claims.

The cited patent is understood to describe adding a carbon source in the following manner:

Examples 1,2,3,5,"The glucose concentration was maintained at between 1% and 2% using fed-batch method till day 4 and at between 0.5 and 1% thereafter";

Example 4: the glucose concentration was maintained at 1.5% till day 5 and no glucose was added thereafter. Glucose was depleted at the end of culturing for 7 days; and

Example 7: 18% glucose was added in several portions from day 1 through day 5 of culturing.

None of the examples or other description of the cited patent teach or suggest addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as claimed. This is further shown below

In Examples 1, 2, 3, and 5 of the cited patent, the glucose concentration is maintained at a constant level, both in the first period as well as in the last period. This means that in each of these periods the rate of addition of the carbon source is equal to the rate of consumption of carbon source by the micro-organism.

However, according to the presently claimed invention, the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-organisms, which has the effect that the concentration of carbon source decreases in time during the addition of the carbon source.

Accordingly, neither of the examples 1, 2, 3, or 5 disclose that the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms.

In example 4 of the cited patent, the glucose concentration is maintained at a constant level until day 5. As discussed above, this means that in this period the rate of addition of the carbon source is equal to the rate of consumption of carbon source by the micro-organism.

However, according to the presently claimed invention, the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-

organisms, which has the effect that the concentration of carbon source decreases in time during the addition of the carbon source.

After day 5, no glucose is added at all. Hence in this period, the requirement of the claim that carbon source is added at the claimed rate is not met. Accordingly, in example 4, the carbon source is not added at a rate below the rate of consumption of the carbon source by the micro-organisms.

In example 7 of the cited patent, 18% glucose was added in several portions from day 1 through day 5 of culturing. This does not provide any information on the rate at which carbon source is added as the amounts of glucose are not given. There is no disclosure or suggestion in the cited patent that the carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms.

As discussed above, the cited patent fails to teach or suggest that a carbon source is added at a rate below the rate of consumption of the carbon source by the micro-organisms. Even less is there any teaching or suggestion in the cited patent that the addition of a carbon source according to the invention results in an increased ARA content in the oil. The cited patent fails to teach or suggest any ARA-content of the oil.

Withdrawal of the Section 102 and Section 103 rejections based on Higashiyama is requested.

To the extent not made moot by the above amendments, the Section 102 and Section 103 rejections of claims 1, 2, 4-6 and 16-28 over Kawashima (U.S. Patent No. 5,322,780), is traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments.

The cited patent fails to teach or suggest, for example, (i) a process for the production of arachidonic acid (ARA) and (ii) adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms

Regarding (i), it is noted that the cited patent is understood to relate to a process for the production of omega 9 polyunsaturated fatty acids (PUFA), see e.g. title. The Examiner will appreciate that arachidonic acid is an omega-6 PUFA, and not an omega 9 PUFA.

For the process of the cited patent, a micro-organism having an ability to produce ARA is mutated to generate a mutant capable of producing omega 9 polyunsaturated fatty acids (col. 2, lines 40-61). However, the mutants of the cited patent do not produce ARA, as required by the presently claimed process. This is also seen in the examples, tables 1 and 2 of the cited patent. The amount of arachidonic acid produced (designated as "Ara" in the tables, 3rd column from the right) by the process of the cited patent is 0 (zero). Hence, the cited patent does not disclose or suggest a process for the production of ARA, as required by the presently claimed invention.

Regarding (ii) noted above, this feed profile for the carbon source is not disclosed or suggested in the cited patent.

Moreover, the cited patent fails to teach or suggest the addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, resulting in an increased ARA content in the oil, as presently claimed.

The cited patent fails to teach or suggest production of ARA, as required by the presently claimed invention, and the process of the cited patent teaches away from

production of ARA, in that omega 9 polyunsaturated fatty acids (PUFA) are produced by the process of the cited patent.

Withdrawal of the Section 102 and Section 103 rejections based on Kawashima is requested.

To the extent not made moot by the above amendments, the Section 102 and Section 103 rejections of claims 1, 2, 4-6 and 16-28 over Akimoto (U.S. Patent No. 5,128,250), is traversed. Reconsideration and withdrawal of the rejections are requested in view of the following distinguishing comments.

The cited patent fails to teach or suggest at least (i) a process for the production of arachidonic acid (ARA) and (ii) adding the carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms.

Regarding (i), it is noted that the cited patent relates to a process for production of highly unsaturated fatty acid having odd number of carbon atoms. Arachidonic acid is a PUFA having 20 carbon atoms. Accordingly, the cited patent teaches the production of a PUFA which is different from ARA, and the presently claimed invention.

Regarding (ii), it is noted that the cited patent does not disclose or suggest any feed profiles for the carbon source. The examples of the cited patent are understood to disclose fermentation in an Erlenmeyer flask (shake flask) in which all carbon source is added at once prior to the onset of the experiment. Accordingly, the cited patent does not disclose or suggest adding a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, as required by the presently claimed invention.

Moreover, the cited patent fails to disclose or suggest addition of a carbon source at a rate below the rate of consumption of the carbon source by the micro-organisms, resulting in an increased ARA content in the oil, as provided by the presently claimed invention.

Finally, the PUFA which is the subject of the cited patent is not ARA, but a PUFA having an odd number of carbon atoms. Accordingly, the cited patent does not provide any teaching or suggestion of how to increase the ARA content in the oil.

Withdrawal of the Section 102 and Section 103 rejections based on Akimoto is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
 B. J. Sadoff
 Reg. No. 36,663

BJS:
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100